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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/768,194	02/02/2004	Douglas Hovey	029318-1001	3657
31049 7590 04/06/2006 ELAN DRUG DELIVERY, INC. C/O FOLEY & LARDNER LLP 3000 K STREET, N.W. SUITE 500 WASHINGTON, DC 20007-5109			EXAMINER GEORGE, KONATA M	
			ART UNIT 1616	PAPER NUMBER
DATE MAILED: 04/06/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/768,194

Applicant(s)

HOVEY ET AL.

Examiner

Konata M. George

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-81 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11, 16-33, 38-54, 59-76 and 81 is/are rejected.
- 7) ☒ Claim(s) 12-14, 34-37, 55-58 and 77-80 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 6/22/04; 7/19/04.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

### **DETAILED ACTION**

Claims 1-81 are pending in this application.

#### ***Information Disclosure Statement***

1. The information disclosure statement (IDS) submitted on June 22, 2004 and July 19, 2004 was noted and the submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner has considered the information disclosure statement.

#### ***Claim Objections***

2. Claim 3 is objected to because of the following informalities: Claim 3 depends from itself which is improper. Appropriate correction is required.

3. The use of the trademark POLYQUAT 10, MIRAPOL and ALKAQUAT has been noted in claims 13, 35, 56 and 78. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

4. Claim 70 is objected to because of the following informalities: Claim 70 states that it depends from "the method of claim 1", however, claim 1 is directed towards a composition and not a method. Appropriate correction is required.

5. Claims 12-14, 34-37, 55-58 and 77-80 are objected to as being dependent upon a rejected base claim.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 17, 20 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 17, 20 and 21 recites the limitation "fluticasone particles" in line 2. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1, 2, 4, 5, 10, 12, 39-41, 44, 48, 53, 54 and 70 are rejected under 35 U.S.C. 102(e) as being anticipated by Wertz et al. (US 2003/0185869).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

It is noted by the examiner that the filing date of the prior art is the same as the date of the provisional application of the instant invention. Examiner is relying on the provisional date of the provisional application of the prior art, which claims the same invention and has a date February 4, 2002.

Example 8, ¶ [0161-0164] teach a method of producing fluticasone propionate particles utilizing lysozyme as a surface stabilizer. The particles are produced by a milling process, which produces fluticasone propionate particles having a mean particles size of 311 nm.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-11, 16-33, 38-54, 59-76 and 81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Karlsson et al. (US 2002/0065256 A1).

Karlsson et al. discloses a process for sterilization of a powdered form of a glucocorticosteroid wherein the glucocorticosteroids are used in the treatment of allergic and/or inflammatory condition of the nose or lungs (abstract). ¶ [0016] teach examples of the glucocorticosteroid used in the composition i.e. fluticasone (e.g. as propionate). ¶ [0017] teach the particle size as less than 10 microns. ¶ [0031] teach the uses of the composition. ¶ [0033] teaches the use of pharmaceutically acceptable additives. ¶ [0035] teach suitable surfactants that can be employed in the composition mention being made to Tyloxapol™ and polyoxyethylene alkyl ethers. ¶ [0036] teach the concentration of the surfactant at about 0.002 to 2% w/w. ¶ [0042] teach the percentage of particles having a specific particles size. ¶ [0044] teach that a suspension containing the active agent and additional ingredients can be produced by sterile filtration. The several examples teach the active agent in concentrations as claimed by applicant. The prior art does not teach specific examples using fluticasone as claimed by applicant.

It is the position of the examiner that it would have been obvious to one of ordinary skill in the art at the time the invention was made to use any of the cited glucocorticosteroids in the instant invention. As paragraph [0016] teaches examples of glucocorticosteroids one of ordinary skill could substitute any one of the glucocorticosteroids listed (i.e. fluticasone) to achieve the same desired results of treating allergic and/or inflammatory condition of the nose or lungs (e.g. chronic obstructive pulmonary disease, asthma, etc.).

***Conclusion***

9. Claims 1-81 are rejected and/or objected too.

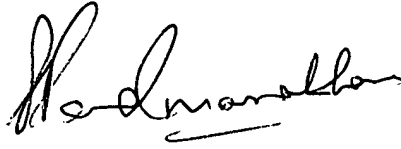
***Telephone Inquiries***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is (571) 272-0613. The examiner can normally be reached from 8AM to 6:30PM Monday to Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached at (571) 272-0887. The fax phone numbers for the organization where this application or proceeding is assigned are (571) 273-8000 for regular communications and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Konata M. George

  
**SREENI PADMANABHAN**  
**SUPERVISORY PATENT EXAMINER**